K133580

APR 2 8 2014

510(k) Summary: Artis one

Company: Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: March 25, 2014

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Importer / Distributor:
Siemens Medical Solution USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center, Gaoxin C.
Ave., 2nd, Hi-Tech Industrial Park
518057 Shenzhen, China
Establishment Registration Number:
3004754211

2. **Contact Person:**
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc., 51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

Trade Name:	Artis one Angiographic System
Classification Name:	Angiographic X-Ray System Image intensified fluoroscopic x-ray system
Common Name:	Angiographic X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1600 21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA, IZI

4. Legally Marketed Predicate Devices

Trade Name:	Artis zee/ zeego with CSX-10 Detector SW VC21
510(k) Clearance:	K122644
Clearance Date:	May 20, 2013
Classification Name:	Image intensified fluoroscopic x-ray system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	OWB
Trade Name:	Artis Q and Q.zen - Modular Angiographic System
510(k) Clearance:	K123529
Clearance Date:	February 26, 2013
Classification Name:	Angiographic X-Ray System Image intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1600 21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA, IZI
Trade Name:	X-LEONARDO Workstation
510(k) Clearance:	K042995
Clearance Date:	November 24, 2004
Classification Name:	Picture archiving and communications system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

5. Device Description:

Siemens Medical Solutions USA, Inc. intends to market an angiography x-ray system the Artis one Angiographic System, SW Version VA10. This 510(k) submission describes several modifications to the previously cleared predicate devices the Artis zee/ zeego K122644; Artis Q and Q.Zen- Modular Angiographic System K123529 and the X-LEONARDO Workstation K042995. The following modifications are made to the cleared predicate devices and developed into the Subject Device the Artis one:

1). A modified Flat Panel detector Trixell pixium 2630S; **2).** A modified collimator MFD; **3).** A modified x-ray tubes assembly MEGALIX Cat Plus 125/40/90-125GW; **4).** A modified Software Version VA10; **5).** A modified C-Arm stand; **6).** A new patient table; **7).** A modified imaging processing system;

8). A modified display; **9).** Modified user Control Modules; **10).** Integrated 3D imaging; **11).** Proposed product claims associated with the above device modifications (see **Section 13** Labeling).

6. Indication for Use:

Artis one is an angiography system developed for diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis one include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by x-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions.

The Artis one can also support the acquisition of position triggered imaging for spatial data synthesis.

7. Substantial Equivalence:

The Artis one Angiography System is substantially equivalent to the commerically available Siemens' Artis zee/ zeego with CSX-10 Detector SW VC21(K122644) angiographic x-ray system with same indication for use for single plane x-ray systems and similar components. The Artis one contains a similar post processing (AXIS Imaging system SW Version VA10); Clear and Care dose reduction features and similar product labeling claims as cleared in the Artis Q and Zen- Modular Angiographic System 510(k) (K123529). The Artis one also produces 3D imaging similar to the cleared X-LEONARDO Workstation 510(k) (K042995). Provided in **Table 1** is a list of all predicate devices for the subject device the Artis one.

Table 1 List of the predicate devices

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Artis zee/ zeego with CSX-10 Detector SW VC21	K122644	05/20/2013	• Indication for use • Hardware components
Artis Q and Q.zen- Modular Angiographic System	K123529	02/26/2013	• Post processing (AXIS Imaging System) • Clear and Care features • Product Labeling Claims
X-LEONARDO Workstation	K042995	11/24/2004	• 3D imaging

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

Artis one Angiography System is designed as a set of components (C-arm, X-ray tube and housing, flat detector, digital imaging system, collimator, generator etc.) that are configured to provide specialized angiography systems. These components are further development of the predicate ones and include minor modifications to existing components.

Discussion:

The components of the subject device have the same technological characteristics as the ones from the predicate device. The technological characteristics do not differ from the predicate systems.

Many comparable parameters remain the same, some differ slightly as shown in the comparison tables (indicated as "similar").

Testing and validation have been completed. A "Concurrent Study" (bench test) as well a Clinical Use Test have been performed on normal and obese adult patients. The image quality has been considered of diagnostic quality and adequate for guidance during interventional procedures. During these studies no adverse effects or complications have been observed and therefore the device is considered safe and effective.

The tests did show that the subject device Artis one with all its components is comparable to the predicate ones and therefore substantial equivalent to the predicate device.

The subject device Artis one does not affect the indication for use nor the intended use of the device nor does it alter its fundamental scientific technology from the 510(k) cleared predicate device Artis zee/ zeego K122644.

9. Non- Clinical Performance Testing

Non-clinical tests were conducted for the Artis one configured with software version VA10 during product development. The modifications described in this Premarket Notification were supported with verification/validation testing and a concurrence study was performed with phantom images.

Siemens claims conformance to a signed statement of conformance to performance standards as follows: IEC 60601-1-2; IEC 60601-1-3; IEC 60601-2-28; IEC 60601-2-43; IEC 60601-2-54; NEMA PS 3.1 - 3.20; ISO 14971; AAMI ANSI ISO 10993-1.

Software documentation for a Major Level of Concern per FDA's Guidance Document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted on the Artis one software during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

EMC/electrical safety was evaluated according to the IEC standards. Siemens certify to conform to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate devices in terms of safety and effectiveness. All testing and validation have been completed.

Clinical testing was not applicable as the Artis one has no new indication for use nor new clinical applications were introduced to the system.

10. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The Artis one Angiography System has the same indication for use as the predicate device Artis zee floor from the Artis zee / zeego family K122644.

The components of the subject device have the same technological characteristics as the ones from the predicate device. The technological characteristics do not differ from the predicate systems.
Testing and validation have been completed. A "Concurrent Study" (bench test) as well a Clinical Use Test did show that the subject device Artis one with all its components is comparable to the predicate ones and therefore substantial equivalent to the predicate device.

The Artis one Angiography System with SW VA10 is substantially equivalent to the commercially available Artis zee/zeego K122644 with all its components as described in the Device Description.

The CARE and CLEAR features are substantially equivalent to the commercially available Artis Q and Artis Q.zen Modular Angiography System

K123529. Postprocessing and 3D Imaging is substantially equivalent to the commercially available X-LEONARDO Workstation K042995.

It is Siemens opinion, that the Artis one Angiography System is substantially equivalent to the listed predicate devices in **Table 1**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control CenterWO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

Siemens Medical Solutions USA, Inc.
Patricia Jones
51 Valley Stream Pkwy.
Malvern, PA 19355 US

Re: K133580
Trade/Device Name: Artis one
Regulation Number: 21 CFR 892.1650
Regulation Name: Interventional Fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: March 21, 2014
Received: March 26, 2014

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

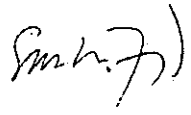
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133580

Device Name
Artis One

Indications for Use *(Describe)*
Artis one is an angiography system developed for diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis one include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whold body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.
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The Artis one can also support the acquisition of position triggered imaging for spatial data systhesis.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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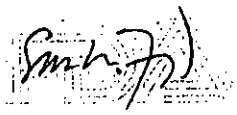
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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